

## CLAIMS

We claim:

1. A method for detecting the presence of an analyte in saliva, comprising:  
a) providing an assay test comprising a reaction site produces a  
detectable signal in presence of an analyte;  
b) placing said reaction site into a mouth of a subject under  
conditions such that saliva from said subject is contacted with said reaction site;  
and  
c) detecting the presence or absence of said detectable signal in said  
reaction site.
2. The method of Claim 1, wherein said detectable signal comprises a  
color change.
3. The method of Claim 1, said assay test comprises a test strip.
4. The method of Claim 3, wherein said test strip comprises an absorbent  
material, wherein said reaction site is located within said absorbent material.
5. The method of Claim 1, wherein said reaction site comprises an  
enzyme, wherein said analyte is a substrate for said enzyme.
6. The method of Claim 1, wherein said reaction site comprises an  
antibody, wherein said antibody binds to said analyte.
- 20 7. The method of Claim 1, wherein said reaction site comprises a  
biosensor.

8. The method of Claim 5, wherein said enzyme produces oxidation and reduction products when reacted with said analyte.

9. The method of Claim 8, wherein said reaction site further comprises a chromogen.

5 10. The method of Claim 8, wherein said chromogen undergoes a color change in the presence of said oxidation and reduction products.

11. The method of Claim 2, wherein said color change is detectable by the human eye.

10 12. The method of Claim 1, wherein in step b), said reaction site is held in said mouth for a sufficient amount of time to generate said detectable signal while said reaction site is in said mouth.

13. The method of Claim 1, wherein in step b), said reaction site is held in said mouth for a sufficient amount of time to generate a detectable signal faster than when said reaction site is held in said mouth for 5 seconds.

15 14. The method of Claim 1, wherein in step b), said reaction site is held in said mouth for 10 seconds or more.

15. The method of Claim 14, wherein in step b), said reaction site is held in said mouth for 30 seconds or more.

20 16. The method of Claim 1, wherein said reaction site comprises a chromogen.

- DR
- mbz*
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17. The method of Claim 16, wherein said chromogen is a non-toxic chromogen.
18. The method of Claim 16, wherein said chromogen is a non-irritant.
19. The method of Claim 16, wherein said chromogen is not an identified carcinogen.
20. The method of Claim 1, wherein said analyte comprises an alcohol moiety.
21. The method of Claim 20, wherein said analyte comprises ethanol.
22. The method of Claim 20, wherein said analyte comprises glucose.
- 10 23. The method of Claim 1, wherein said analyte comprises a ketone moiety.
24. The method of Claim 23, wherein said analyte comprises a ketone body.
25. The method of Claim 1, wherein said analyte comprises prostate-specific antigen.
- 15 26. The method of Claim 1, wherein said analyte comprises melatonin.
27. The method of Claim 1, wherein said analyte comprises lactoferrin.
28. A system comprising a plurality of assay tests for analyzing a sample for the presence of glucose, said system comprising a plurality of glucose assay tests within a delivery system, wherein said delivery system comprises two or more folded

panels, wherein said panels comprise a width X cm, a length Y cm, and a thickness Z cm, wherein  $X * Y * Z$  is less than 100 cm<sup>3</sup>.

29. The system of Claim 28, wherein  $X * Y * Z$  is less than 30 cm<sup>3</sup>.  
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30. The system of Claim 29, wherein  $X * Y * Z$  is less than 10 cm<sup>3</sup>.  
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5 31. The system of Claim 28, wherein the ratios of X:Z and Y:Z are greater than 20:1.  
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32. The system of Claim 28, wherein X is 6 cm or less, Y is 8.5 cm or less, and Z is 2 mm or less.  
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10 33. The system of Claim 28, wherein said assay tests are stable in said delivery system for at least one month.  
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34. The system of Claim 28, wherein said assay tests are stable in said delivery system for at least one year.  
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35. The system of Claim 28, wherein said assay tests produce a detectable signal in the presence of glucose.  
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15 36. The system of Claim 35, wherein said detectable signal comprises a color change.  
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37. The system of Claim 36, wherein said color change is interpretable without the use of a meter.  
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20 38. The system of Claim 28, wherein said assay test comprises a non-toxic chromogen.  
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39. The system of Claim 28, wherein said assay test comprises a non-irritant chromogen.

40. The system of Claim 28, wherein said assay test comprises a non-carcinogenic chromogen.

5 41. The system of Claim 28, further comprising safety materials or time consuming materials.

42. A assay delivery system comprising:

a) a rigid package insert; and

b) two or more individually packaged glucose assay tests mounted on said rigid package insert.

10 43. The delivery system of Claim 42, wherein said rigid package insert comprises a width of X cm, a length of Y cm, and a thickness of Z cm, wherein  $X * Y * Z$  is less than  $100 \text{ cm}^3$ .

44. The system of Claim 43, wherein  $X * Y * Z$  is less than  $30 \text{ cm}^3$ .

15 45. The system of Claim 44, wherein  $X * Y * Z$  is less than  $10 \text{ cm}^3$ .

46. The system of Claim 43, wherein the ratios of X:Z and Y:Z are greater than 20:1.

47. The system of Claim 43, wherein X is 6 cm or less, Y is 8.5 cm or less, and Z is 2 mm or less.

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48. The system of Claim 42, wherein said two or more assay tests consist of two individually packaged glucose assay tests.
49. The system of Claim 42, wherein said glucose assay tests comprise test strips.
50. The system of Claim 42, further comprising safety materials or time consuming materials.
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51. A system comprising a plurality of assay tests for analyzing a sample for the presence of ketone bodies, said system comprising a plurality of ketone body assay tests within a delivery system, wherein said delivery system comprises two or more folded panels, wherein said panels comprise a width X cm, a length Y cm, and a thickness Z cm, wherein  $X * Y * Z$  is less than 100 cm<sup>3</sup>.
52. The system of Claim 51, wherein  $X * Y * Z$  is less than 30 cm<sup>3</sup>.
53. The system of Claim 52, wherein  $X * Y * Z$  is less than 10 cm<sup>3</sup>.
54. The system of Claim 51, wherein the ratios of X:Z and Y:Z are greater than 20:1.
55. The system of Claim 51, wherein X is 6 cm or less, Y is 8.5 cm or less, and Z is 2 mm or less.
56. The system of Claim 51, wherein said assay tests are stable in said delivery system for at least one month.
- 20 57. The system of Claim 51, wherein said assay tests are stable in said delivery system for at least one year.

58. The system of Claim 51, wherein said assay tests produce a detectable signal in the presence of ketone body.

59. The system of Claim 58, wherein said detectable signal comprises a color change.

5 60. The system of Claim 59, wherein said color change is interpretable without the use of a meter.

61. The system of Claim 51, wherein said assay test comprises a non-toxic chromogen.

10 62. The system of Claim 51, wherein said assay test comprises a non-irritant chromogen.

63. The system of Claim 51, wherein said assay test comprises a non-carcinogenic chromogen.

64. The system of Claim 51, further comprising safety materials or time consuming materials.

15 65. A assay delivery system comprising:

a) a rigid package insert; and

b) two or more individually packaged ketone body assay tests

mounted on said rigid package insert.

20 66. The delivery system of Claim 65, wherein said rigid package insert comprises a width of X cm, a length of Y cm, and a thickness of Z cm, wherein X \* Y \* Z is less than 100 cm<sup>3</sup>.

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67. The system of Claim 66, wherein  $X * Y * Z$  is less than  $30 \text{ cm}^3$ .
68. The system of Claim 67, wherein  $X * Y * Z$  is less than  $10 \text{ cm}^3$ .
69. The system of Claim 66, wherein the ratios of  $X:Z$  and  $Y:Z$  are greater than 20:1.
- 5        70. The system of Claim 66, wherein  $X$  is 6 cm or less,  $Y$  is 8.5 cm or less, and  $Z$  is 2 mm or less.
- 10      71. The delivery system of Claim 65, wherein said two or more assay tests consist of two individually packaged ketone body assay tests.
72. The delivery system of Claim 65, wherein said ketone body assay tests comprise test strips.
73. The delivery system of Claim 65, further comprising safety materials or time consuming materials.